

CLAIMS

1. An apparatus for separating motile spermatozoa from non-motile spermatozoa in a liquid sample, the apparatus comprising (i) a vessel having a sample receiving inlet, a filtered sample outlet and a sample separation filter mounted therebetween, the sample separation filter having a sample-receiving surface and an opposed surface, and the sample separation filter being effective ~~substantially~~ to prevent flow of the sample therethrough, but permitting passage of motile spermatozoa therethrough when said opposed surface of said sample separation filter is placed in contact with a liquid medium and (ii) means for supplying a liquid to said opposed surface of said filter.
2. An apparatus according to claim 1, wherein the sample separation filter is of a gel or foam construction.
3. An apparatus according to claim 1, wherein the filter is fibrous.
4. An apparatus according to claim 3, wherein the fibrous filter is made of glass wool or polypropylene.
5. An apparatus according to any preceding claim, wherein the sample additionally comprises non-motile spermatozoa and spermatozoa with reduced motility.
6. An apparatus according to ~~any preceding claim~~ ^{claim 1}, comprising a spermatozoa detection means on the outlet side of the sample separation filter, and spaced therefrom.
7. An apparatus according to claim 6, wherein the detection means is integral with the apparatus.
8. An apparatus according to claim 6, wherein the detection means is a separable component of the apparatus for inserting into the apparatus before, during or after placing the sample separation filter in contact with the liquid medium.
9. An apparatus according to ~~any preceding claim~~ ^{claim 1}, wherein the filter has a thickness of 100-2000µm.
10. An apparatus according to claim 9, wherein the filter has a thickness of 200-1000µm, preferably 400-800µm.
11. An apparatus according to claim 10, wherein the filter has a thickness off about 600µm.

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 12. An apparatus according to ~~any preceding claim~~ ^{claim 14}, wherein the filter has a minimum particle retention size of 5-100µm, preferably 8-60µm, more preferably 10-40µm.

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 13. An apparatus according to ~~any preceding claim~~ ^{claim 2}, wherein the filter has an underlying grid lattice for supporting the ~~filter~~ ^{filter apparatus}.

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 14. An apparatus according to ~~any of claims 6 to 13~~ ^{claim 6}, wherein a reagent or a combination of reagents which is/are directly or indirectly capable of generating a visual signal on interaction with spermatozoa is/are located in the spermatozoa detection means.

15. An apparatus according to claim 14, wherein the reagent or combination of reagents include antibodies that detect an antigen present on spermatozoa and are capable of binding spermatozoa.

16. An apparatus according to claim 15, wherein spermatozoa, when immobilised by the antibodies, can be visually detected using a visually detectable reagent which binds to spermatozoa.

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 17. An apparatus according to ~~any of claims 6 to 16~~ ^{claim 6}, wherein a spermatozoa chemoattractant is located in the spermatozoa detection means.

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 18. An apparatus according to ~~claim 17~~ ²², wherein the spermatozoa chemoattractant is located in a portion of the spermatozoa detection means distal from the sample separation filter.

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 19. An apparatus according to ~~any of claims 6 to 18~~ ^{claim 6}, wherein a pick-up zone is located either in the sample separation filter or the spermatozoa detection means, said pick-up zone comprising a reagent or combination of reagents which is/are capable of binding to spermatozoa and being transported therewith to a detection area of the spermatozoa detection means.

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 20. An apparatus according to ~~claim 19~~ ²⁴, wherein the reagent or combination of reagents of the pick-up zone include antibodies that detect an antigen present on spermatozoa.

25 21. An apparatus according to claim 20, wherein the antibodies that detect an antigen present on spermatozoa are detectably labelled.

22. An apparatus according to claim 21, wherein the antibodies that detect an antigen present on spermatozoa are detectably labelled with gold particles.

23. An apparatus according to claim 20, ~~claim 21 or claim 22~~, wherein the antibodies that are located in a detection area of the spermatozoa detection means recognise a different spermatozoa antigen compared to the antibodies located in the pick-up zone.

24. An apparatus according to claim 20, ~~claim 21 or claim 22~~, wherein the antibodies that are located in a detection area of the spermatozoa detection means recognise the same spermatozoa antigen as the antibodies located in the pick-up zone.

25. An apparatus according to ^{Claim 6} ~~any of claims 6 to 24~~, wherein the spermatozoa detection means comprises a spermatozoa acrosome-lysing reagent and a means for detecting pH change.

31 26. An apparatus according to ³⁰ ~~claim 25~~, wherein the spermatozoa acrosome-lysing reagent is a lysis buffer.

27. An apparatus according to claim 26, wherein the lysis buffer comprises Proteinase K or the calcium ionophore A24297.

33 28. An apparatus according to ³⁰ ~~claim 25, claim 26 or claim 27~~, wherein the means for detecting pH change is a pH sensitive probe.

15a 29. An apparatus according to claim 25, ~~claim 26 or claim 27~~, wherein the means for detecting pH change is a pH indicator reagent capable of visually detecting a pH change.

35 30. An apparatus according to ³⁴ ~~claim 29~~, wherein the pH indicator reagent is bromocresol purple.

36 31. An apparatus according to ^{Claim 1} ~~any of the preceding claims~~, wherein the sample receiving surface of the sample separating filter contains an enzymatic liquefaction agent.

32. A male fertility testing kit comprising an apparatus according to any one of claims 6 to 31, the kit comprising a liquid release mechanism, wherein upon activation of the liquid release mechanism, liquid from a liquid supply is applied to the sample filtered end of the sample separation filter to provide liquid communication with the spermatozoa detection means.

33. A kit according to claim 32, wherein the detection means is a separable component of the kit.

34. The kit of claim 32 or claim 33, comprising an integral liquid supply.

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46. The method of claim 45, wherein the filter is the filter contained within the apparatus of any of claims 1 to 31.
47. The method of claim 43, wherein the filter is the filter contained within the kit of any of claims 32 to 44.
- 5 48. An apparatus for separating motile spermatozoa from non-motile spermatozoa substantially as hereinbefore described with reference to the accompanying drawings.
49. A male fertility testing kit substantially as hereinbefore described with reference to the accompanying drawings.
50. A method for detecting an analyte in a sample substantially as hereinbefore described
10 with reference to the accompanying drawings.
51. A method of detecting motile spermatozoa in a sample substantially as hereinbefore described with reference to the accompanying drawings.

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